IAHCSMM Fall 2000 Meeting

Reuse in the Department

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FDA's Position Historically

- Reprocessing in Hospitals/Clinics (Compliance Policy Guide 300.500)
- Any Person Reprocessing a single use device (SUD) Is a "Manufacturer"
- Premarket Submissions Were Not Requested
- Enforcement Discretion for Hospital Reprocessing

Summary of FDA Activities

- Active in Conferences/Meetings
- Reviewed Published Literature
- Conducted Inspections of 3rd Party Reprocessors
- Reviewed/Analyzed MDR Data

Summary of FDA Activities
(continued)

- Conducted In Vitro Research - biopsy forceps, PTCA and EP Catheters, sutures, etc.
- Published Proposed Reuse Strategy - November, 1999
- Open Public Meeting - December, 1999
- Issued Draft Guidances - February, 2000
- Issued Final Guidance - August, 2000

Reuse

- FDA's policy is changing because:
  - Types of single-use devices being reprocessed
  - FDA laboratory findings
  - Widespread practice but little data on safety or effectiveness
  - Single-use labels not clearly meaningful
  - Patients are not informed -- experimentation?

FDA Laboratory Research Findings

- CDRH Office of Science and Technology (OST) In-Vitro Research on Biopsy Forceps, PTCA and EP Catheters, Sutures, etc.
- General Conclusions Cannot Be Made of the Effects of Reprocessing on Any SUDs

FDA Laboratory Research Findings (continued)

- Performance Factors May Not be Affected for Some Products, but Significant Change for Others; e.g., Sutures
- Cleaning Difficult for Some Device Models But Not for Others Developed by Same OEM; e.g., PTCA Catheters

FDA Laboratory Research Findings (continued)

- Each Device Must Be Carefully Examined to Determine the Particular Problems With Cleaning, Disinfection and Resterilization
- OST Findings on Safety of Cleaning Published: Merritt et al., J. Biomed Materials Res 53:131-136, 2000

FDA Laboratory Findings
(continued)

- OST Will Continue Research Activities; Data From Other Sources May be Needed

Comments to FDA Documents

- Over 180 Comments Received; Sample Comments:
  - Hospitals Currently Over-Regulated
  - Timeframes too Short for Hospitals
  - Use the Existing Medical Device Classification System
  - Make Worksheets Available
  - Modify Scheme to Only Have Two Risk Categories

Comments to FDA Documents
(continued)

- Some Devices Rated a Higher Risk, and Some Lower, Than FDA's Evaluation
- Inconsistencies in the Categorization of Similar Devices
- Visual Inspection of a Reprocessed SUD Shifts the Burden of Determining If a Device Is Safe and Effective to the User

Comments to FDA Documents
(continued)

- Establish an Appeals Process For the Risk Level Determination
- Third-party Reprocessors Expressed the Need for More Time to Get Premarket Submissions Cleared

FDA's New Position: Final Guidance Document

- Increased Regulatory Oversight for Reprocessing
- Same Requirements for Hospitals and Third-Party Reprocessors
- Collapsed Two Draft Guidance Documents from February 2000 into one Final Guidance Document published August 2000 (http://www.fda.gov/cdrh/reuse):

Overview of Final Guidance Document

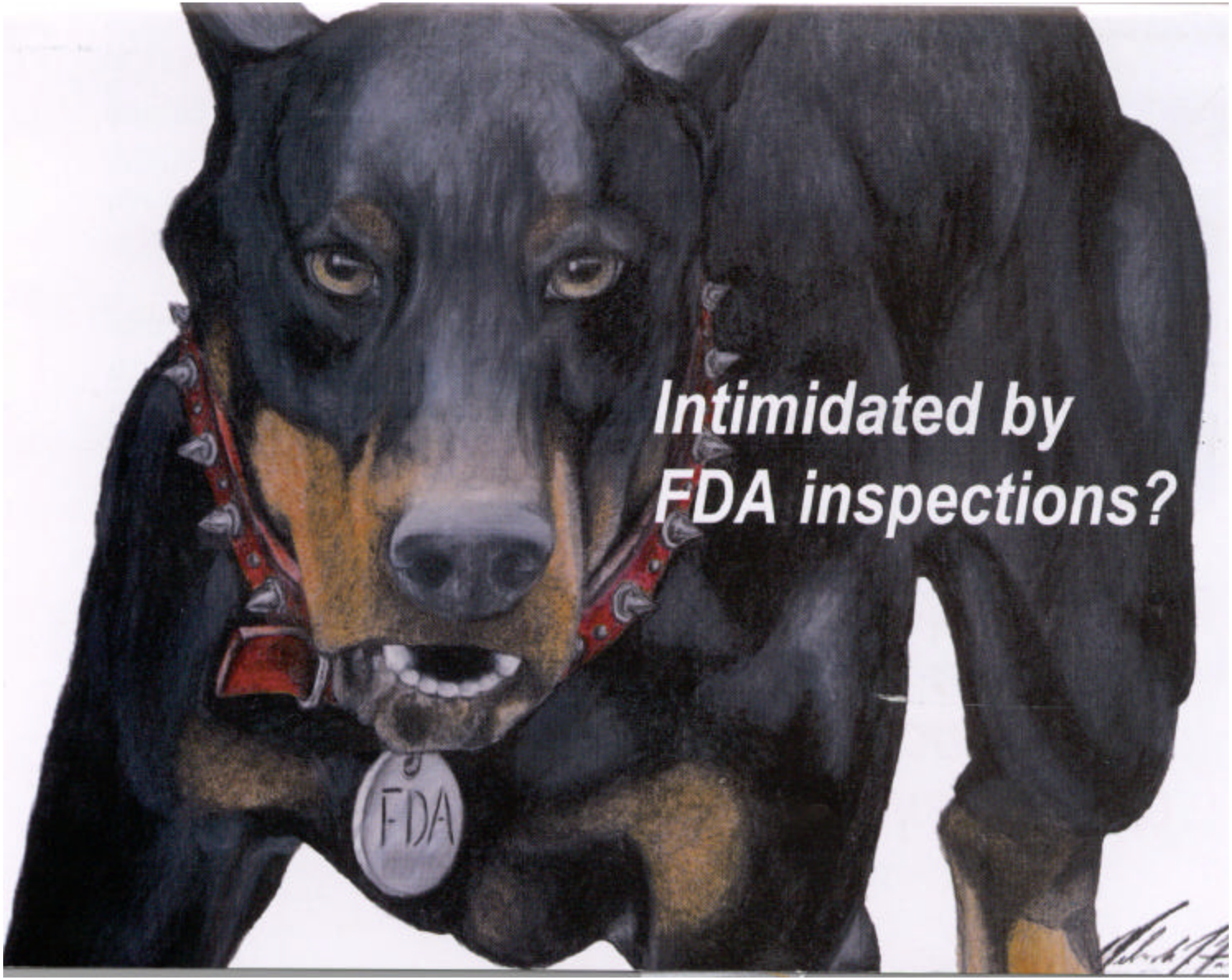
- Applicable to Third-Party Reprocessors and Hospital Reprocessors of SUDs Only
- Not Applicable to Permanently Implantable Pacemakers, Opened but Unused Devices, Healthcare Facilities That Are Not Hospitals
- Provides Expanded List of Known Reprocessed Devices Identifying Classification, Type of Premarket Submission and Exemption Status

Overview of Final Guidance Document (continued)

- Utilizes Device Classification System (Class I, II, III) instead of Risk Prioritization Scheme for determining submission timeframes
- Specifies Premarket Submission Timeframes From Date of Guidance Finalization:
  - Class III 6 months
  - Class II 12 months
  - Class I 18 months

Overview of Final Guidance Document (continued)

- Regulatory Requirements That Will Be Enforced for All Reprocessors After Guidance Phase-In
  - Registration and Listing
  - Medical Device Reporting
  - Tracking
  - Corrections and Removals
  - Quality Systems Regulation
  - Labeling
  - Premarket Requirements
- Hospitals Allowed 12 Months from Guidance Finalization to Comply With Non-Premarket Requirements (August 2001)


Intimidated by
FDA inspections?
FDA

Enforcement Timeframes Do Not Preclude FDA From Taking Immediate Action Against an Unsafe Device at Any Time

Classification System

- The Basis for Determining the Process for Marketing a Medical Device in the United States
- The Classes Are:
  - Class I: General Controls
  - Class II: General Controls and Special Controls
  - Class III: General Controls, Special Controls, and Premarket Approval

How To Determine the Regulatory Class of a Medical Device

- Title 21 Code of Federal Regulations (CFR) Parts 862-892
- Product Code Classification Database (http://www.fda.gov/cdrh/procode.html)

Class III Devices

- File 510(k) or PMA Within 6 Months After Issuance of Final FDA Enforcement Guidance; due February 14, 2001
- Submission Must Be of Sufficient Quality So That FDA Can Perform Substantive Review
- Reprocessor Must Receive Substantial Equivalent (SE) Determination or Approval to Market Device Within 6 Months of Filing Deadline; due August 14, 2001

Class II Devices

- Must Submit 510(k) or PMA Within 12 Months of Issuance of Final Enforcement Guidance; due August 14, 2001
- Submission Must Be of Sufficient Quality So That FDA Can Perform Substantive Review
- Reprocessor Must Receive SE Determination or Approval to Market Device Within 6 Months of Filing Date; due February 14, 2002

Class I Devices

- 510(k) or PMA Submitted Within 18 Months of Issuance of Final Enforcement Guidance; due February 14, 2002
- 510(k) or PMA Must Be of Sufficient Quality So That FDA Can Perform Substantive Review
- Reprocessor Must Receive SE Determination or Approval to Market Device Within 6 Months of Filing Date; due August 14, 2002

Percentage of Devices in Each Class

- Class I - 46%
- Class II - 47%
- Class III - 7%

Where is FDA Going From Here?

- Establishing a Formal Auditing Contract With JCAHO; Currently Gathering Reuse Information
- States May Also Be Used in Auditing.
- Initiating Extensive Outreach Activities for Hospitals

Where Is FDA Going From Here?
(continued)

- Obtained Considerable Resources for Reuse Implementation
- Encouraging the Development of Standards
- Continuing Laboratory Research
- Other Types of Reprocessors Will Be Considered Later for Regulatory Oversight

Reuse - Implementation

- JCAHO to:
  - Determine extent of reprocessing in hospitals
  - Audit most hospital reprocessors
  - Help hospitals improve their practices

CDRH Outreach Activities on Reuse

- Completed or Planned FDA Activities
  - Provide Updated Information on FDA website
  - Coordination With Hospital Associations for Information Dissemination; e.g., websites, newsletters, articles, etc.
  - Letters to All U.S. Hospitals
  - CD-ROM Training for Hospitals
  - Letters to Third-Party Reprocessors on Regulatory Requirements
  - Satellite Teleconference December 13, 2000

Other Reprocessors

- No FDA Oversight Currently for Other Reprocessors
- Will Consider Enforcement Policy for Them as Hospital and Third-party Reprocessor Requirements Phase-In